



The Sperm & Embryo Bank of New Jersey, Inc.[®] SEBNJ

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August 17, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 97N-484R

I am in favor of the attached document submitted by Russ Bierbaum of The American Association of Tissue Banks Reproductive Council. It strongly urges the FDA to look favorably upon those comments (Attachment 1)

In addition to the attached comments and as an overall comment to donor suitability, I strongly favor and support the FDA position proposed in Publication No. FS 02-1 (February 02), (Attachment 2), that all donors regardless of whether they are anonymous donors, directed donors or client depositors (individuals storing sperm and/or embryos for their intimate partners) to be tested accordingly for the following:

Hepatitis B and C Viruses (HBV and HCV)
Human Immunodeficiency Virus (HIV 1 and 2)
Human T-Lymphotropic Virus, Types I and II

In addition, I favor the use of NAT tests to give sperm banks and HCT/Ps facility the ability to access the current status of all the individuals for HIV and HCV in as much as they fall within the fresh "HCT/Ps" model

I look forward to the implementation of the final draft.

Sincerely yours,

Albert Anouna, B.S., HCLD
Director/CEO

Attachments

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